UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,594	05/24/2005	Eldon R Smith	355908-2760	9302

38706 7590 07/24/2007

FOLEY & LARDNER LLP
1530 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
07/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,594	SMITH ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Applicant recites "the process of wherein..." without indicating what type of process is being used in the claim. For the purposes of examination, the Examiner is assuming that applicant intended to make claim 5 dependent from claim 1, and is examining the claim on the merits accordingly.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,136,308 to Tremblay et al.

In the specification and figures, Tremblay discloses a method of treating stress, resulting in abnormal functioning of a body organ by administering to a mammalian patient an aliquot of autologous blood that has been subjected to oxidative stress and

electromagnetic (ultraviolet) radiation (see column 1, lines 25-40, column 2, lines 45-67 column 6, lines 10-15, 31-33). Cardiac instability, arrhythmia, sudden cardiac death, and SIDS are all examples of abnormal body organ functioning, since the organs (namely, the heart), function abnormally to cause patient ailment or death. Accordingly, the Tremblay disclosure drawn to the treatment of stress and its adverse effects (including abnormal body organ function), anticipates the method claimed by applicant.

With regard to claims 7-9, Trembly discloses the step of simultaneous use of ultraviolet light, bubbling an oxygen/ozone mixture through the aliquot, and heating the aliquot to 45C (see column 4, lines 1-67, column 3, lines 1-5, 66-67).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,136,308 to Tremblay.

In the specification and figures, Tremblay discloses the method substantially as claimed by applicant (see rejection above), with the exception of the step of observing a particular QT-c interval prior to treatment.

Applicant does not actually claim the step of observing or using the patient's QT-c interval in the method claimed in claim 1. Nonetheless, if the claimed QTc interval is

indicative of a cardiac disorder, the claimed interval is encompassed by Tremblay's disclosure of treating abnormal organ function. Tremblay's disclosure reasonably suggests to a person of ordinary skill in the art that a health care provider would observe an abnormal organ function, such as the QT-c interval claimed by applicant (since applicant indicates the claimed QT-c interval is an indicator of cardiac disorder), prior to treating the patient, and then treat the patient with the claimed blood stressing method. Accordingly, it is the position of the Examiner that the Tremblay reference suggests the method claimed by applicant.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,136,308 to Tremblay et al in view of US 4,968,483 to Mueller et al.

In the specification and figures, Tremblay discloses the method substantially as claimed by applicant (see rejection above), including the aliquot size of 0.1-400mL (see column 3, lines 66-67), with the exception of injecting the stressed aliquot intramuscularly. Mueller teaches a method of hematological therapy comprising the steps of removing a patient's blood, subjecting it to oxidative, temperature, and electromagnetic stress, and reinfusing the stressed blood to the patient intravenously or intramuscularly in order to treat the patient (see columns 1-2, sep column 2, lines 10-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the step of intramuscular injection as disclosed by Mueller of the stressed aliquot as disclosed by Tremblay in order to treat the patient.

9. As an alternative to the 35 U.S.C. 102(b) rejection presented above, claims 1, 3, 4, and 6-9 are rejected as being unpatentable over US 6,136,308 to Tremblay in view of US 5,599,673 to Keating et al.

With regard to claims 1 and 7-9, Tremblay discloses a method of treating stress, resulting in abnormal functioning of a body organ by administering to a mammalian patient an aliquot of autologous blood that has been subjected to oxidative stress and electromagnetic (ultraviolet) radiation (see column 1, lines 25-40, column 2, lines 45-67 column 6, lines 10-15, 31-33) (see rejection above). Tremblay does not specifically disclose that a long QT-c interval (which is a QT interval normalized for a specific patient's heart rate) is an abnormal function of a body organ. However, Keating discloses that a long QT interval is the result of an abnormal cardiac repolarization, which reasonably suggests an abnormal body organ function (see column 1, lines 30-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the method disclosed by Tremblay to treat a patient with a cardiac disorder such as a long QT interval, since Keating teaches that a long QT interval is an abnormal body organ function.

With regard to claims 3 and 4, Keating teaches that long QT syndrome creates cardiac arrhythmias and sudden death, suggesting the treatment of those conditions when treating abnormal body organ functions such as long QT syndrome (see column 1, lines 30-50).

With regard to claim 6, Keating teaches that patients with a QT interval of greater than 0.44 seconds are classified as those with a long QT interval (see column 4, lines

10-15), suggesting that patients with a QT interval of 0.44 seconds or greater would be those selected for treatment by the method disclosed by Tremblay.

10. As an alternative to the 35 U.S.C. 102(b) rejection presented above, claims 2 and 5 are rejected as being unpatentable over US 6,136,308 to Tremblay in view of US 5,599,673 to Keating et al, further in view of US 6,208,897 to Jorgenson et al.

In the specification and figures, Tremblay and Keating suggest the method as claimed by applicant with the exception of treating cardiac instability and SIDS patients. Jorgenson discloses that SIDS victims have a history of long QT syndrome, resulting in cardiac instability (see column 3, lines 17-32). The combination of the references reasonably suggest to one of ordinary skill in the art that if cardiac instability and SIDS is associated with a long QT interval as disclosed by Jorgenson, and a long QT interval is an abnormal body organ function as disclosed by Keating, then the method disclosed by Tremblay would be an appropriate treatment for cardiac instability and SIDS. Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to treat cardiac instability and SIDS-susceptible patients with long QT intervals with the method disclosed by Tremblay in order to correct the abnormal body organ function.

11. As an alternative to the 35 U.S.C. 103(a) rejection of claim 10 presented above, claim 10 is rejected as being unpatentable over US 6,136,308 to Tremblay in view of US 5,599,673 to Keating et al, further in view of US 4,968,483 to Mueller et al.

In the specification and figures, Tremblay and Keating suggest the method substantially as claimed by applicant (see rejection above), including the aliquot size of

0.1-400mL (see Tremblay column 3, lines 66-67), with the exception of injecting the stressed aliquot intramuscularly. Mueller teaches a method of hematological therapy comprising the steps of removing a patient's blood, subjecting it to oxidative, temperature, and electromagnetic stress, and reinfusing the stressed blood to the patient intravenously or intramuscularly in order to treat the patient (see columns 1-2, sep column 2, lines 10-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the step of intramuscular injection as disclosed by Mueller of the stressed aliquot in the method suggested by Tremblay and Keating in order to treat the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
19 July 07